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## **Draft NIH Embryonic Stem Cell Regulations Consistent with CIRM Standards: CIRM Funding Still Needed for Broad Array of Research Areas**

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San Francisco, Calif., April 17, 2009 – The National Institutes of Health announced draft guidelines for research using human embryonic stem cells that are largely consistent with regulations developed by the California Institute for Regenerative Medicine, the National Academies of Science and other national and international organizations.

CIRM applauds the speed with which the NIH prepared these draft regulations. Having clear regulations in place, and the resulting availability of NIH funds for embryonic stem cell research, will speed a field of research that CIRM considers critical for the development of new therapies.

The draft regulations allow research only with human embryonic stem cell lines derived from embryos created for in vitro fertilization and no longer required for reproductive use. Researchers must demonstrate that lines proposed for research use comply with specific donation, consent and disclosure requirements.

The conditions required by the NIH are largely consistent with requirements CIRM has developed for derivation performed by our grantees, according to Geoff Lomax, senior officer for medical and ethical standards. "For our grantees working with lines derived under CIRM standards, these regulations open the door to broader sources of funding, expanding important research in California," Lomax said.

Lomax said that under both sets of guidelines, researchers hoping to use a particular stem cell line must prove that the couple who donated the embryo knew that they would not personally benefit from the work, that they would not benefit from possible commercial applications of the cells, and that they could not place restrictions on the type of research performed with the cell line, among other conditions. He added that CIRM may need to make a minor revision to its regulations requiring that couples be specifically informed of all options for disposing of their excess embryos before donating to research.

Lomax added that there are important avenues of research funded by CIRM that are prohibited under the draft regulations. These include the creation of new stem cell lines, and any work with lines created through nuclear transfer (sometimes called therapeutic cloning) or parthenogenesis, in which the egg is stimulated to begin division without fertilization.

"CIRM remains a critical source of funding in California for work that is not eligible for funding by the NIH but that has important scientific value," Lomax said. For example, embryonic stem cell lines created through parthenogenesis are genetically identical to the donor and could be an important source of stem cells for therapies.

Until the draft regulations are finalized the NIH is pausing funding of embryonic stem cell research grants. After the 30-day public comment period the NIH will publish final guidelines and resume funding of new grants. At that time researchers must prove that lines they intend to study were derived in ways that comply with the regulations. Lomax said that this evaluation process could eliminate some lines that had previously been available for federal funding under the regulations in place since August 9, 2001.

Draft regulations can be found here: <http://stemcells.nih.gov/policy/pages/2009guidelines.aspx>

**About CIRM** CIRM was established in 2004 with the passage of Proposition 71, the California Stem Cell Research and Cures Act. The statewide ballot measure, which provided \$3 billion in funding for stem cell research at California universities and research institutions, was overwhelmingly approved by voters, and called for the establishment of an entity to make grants and provide loans for stem cell research, research facilities, and other vital research opportunities. To date, the CIRM governing board has approved 279 research and facility grants totaling more than \$693 million. For more information, please visit [www.cirm.ca.gov](http://www.cirm.ca.gov).

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